4,338,317

#12

(IND) became effective was on November 19, 1975.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: December 30, 1991. The applicant claims December 24, 1991, as the date the new drug application (NDA) for LUVOX™ (NDA 20–243) was initially submitted. However, FDA records indicate that NDA 20–243 was submitted and received on December 30, 1991.

3. *The date the applications was approved*: December 5, 1994. FDA has verified the applicant's claim that NDA 20–243 was approved on December 5, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 23, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 23, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 17, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–10073 Filed 4–21–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0038]

Determination of Regulatory Review Period for Purposes of Patent Extension; SERZONE®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SERZONE® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SERZONE® (nefazodone hydrochloride). SERZONE® is indicated for treatment of depression. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SERZONE® (U.S. Patent No. 4,338,317) from Bristol-Myers Squibb, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 1, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SERZONE® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SERZONE® is 4,420 days. Of this time, 3,216 days occurred during the testing phase of the regulatory review period, while 1,204 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* November 17, 1982. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on November 17, 1982.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* September 6, 1991. FDA has verified the applicant's claim that the date the new drug application (NDA) for SERZONE® (NDA 20–152) was initially submitted was on September 6, 1991.

3. *The date the application was approved:* December 22, 1994. FDA has verified the applicant's claim that NDA 20–152 was approved on December 22, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 23, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 23, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 17, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–10077 Filed 4–21–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94E–0071]

Determination of Regulatory Review Period for Purposes of Patent Extension; Zosyn®; Correction

AGENCY: Food and Drug Administration.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the notice that appeared in the **Federal Register** of August 30, 1994. The document announced FDA's determination of the regulatory review period for purposes of patent extension for Zosyn® (tazobactam sodium and piperacillin sodium). The document was published with some errors. The document incorrectly stated:

FDA has determined that the applicable regulatory review period for Zosyn® is 1,819 days. Of this time, 1,038 days occurred during the testing phase of the regulatory review period, while 781 days occurred during the approval phase.

1. The date an exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: October 31, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn® (IND 31,705) became effective. However, IND 31,705 was received on June 14, 1988, and it was placed on clinical hold on July 1, 1988. It was removed from clinical hold on October 31, 1988, making the IND effective date October 31, 1988.

It should have stated:

FDA has determined that the applicable regulatory review period for Zosyn® is 1,906 days. Of this time, 1,125 days occurred during the testing phase of the regulatory review period, while 781 days occurred during the approval phase.

1. The date an exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: August 5, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn® (IND 31,705) became effective. However, IND 31,705 was received on June 14, 1988, and it was placed on clinical hold on July 1, 1988. It was removed from clinical hold on August 5, 1988, making the IND effective date August 5, 1988.

This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: In FR Doc. 94–21286, appearing on page 44738 in the **Federal Register** of August 30, 1994, the following corrections are made:

On page 44739, in the first column, in the third full paragraph, in the third line, "1,819" is corrected to read "1,906" and in the fourth line, "1,038" is corrected to read "1,125"; in the same column, in the fourth line from the bottom, "October 31, 1988" is corrected to read "August 5, 1988"; and in the second column, in the fifth and sixth lines, "October 31, 1988" is corrected to read "August 5, 1988".

Dated: April 17, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–10074 Filed 4–21–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0012]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sonic Accelerated Fracture Healing System (SAFHS®)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SAFHS® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device SAFHS®. SAFHS® is indicated for the acceleration of the time to a healed fracture for fresh, closed, distal radius (Colle's) fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SAFHS® (U.S Patent No. 4,530,360) from Exogen, Inc., and the Patent and